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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,385	06/19/2007	Michael John Moorhouse	3691-062550	6983

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
02/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,385	MOORHOUSE ET AL.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed December 13, 2010 in response to the Office Action of August 12, 2010 is acknowledged and has been entered. Applicant's election without traverse of Group II, and the species of Table 2 is acknowledged.

Applicant has cancelled claims 1-48 and added new claims 49-54 asserting that the claims read on Group II. This is found persuasive. It is noted that new claims 49-54 limit the species to the genes of clusters #9, #12 and #13 found in table 2.

Claims 49-54 are currently under consideration.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 15. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See p. 40-line 8. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: The specification refers to Supplemental Data Tables that do not appear to be part of the specification as filed. See for example: p. 44, lines 12-17; p.45-lines 2-25; p.46, lines 5-15; and p.48-line 13.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 49-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 recites the limitation "step e)" in reference to the preceding steps. There is insufficient antecedent basis for this limitation in the claim because there is no step e). Thus claim 49 and its dependent claims are indefinite.

Claim 50 contains the trademark/trade name Affymetrix GeneChip. See Affymetrix (http://www.affymetrix.com/estore/, 2009). Where a trademark or trade name is used in a claim

as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a substrate and, accordingly, the identification/description is indefinite.

Additionally, cluster 12 contains two genes that have no gene names and are only identified by Unigene Ids HS.356623 and HS.454253. However, Unigene Ids HS.356623 and HS.454253 have been retired. See UniGene (Hs.356623, 02/08/2011) and UniGene (HS.454253, 02/08/2011). Thus, the scope of the claims is indefinite because it cannot be determined what is encompassed by these unidentified genes and the metes and bounds of the claims cannot be determined.

6. Claims 49-54 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: obtaining a sample from an AML affected subject for which the prognosis is to be determined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 49-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for A method for determining the prognosis for an AML affected subject, said method comprising the steps of: **a) obtaining a sample from the AML affected subject;** b) determining, by means of assays conducted on a substrate, a level of expression for each of at least five cluster-specific genes selected from one of the clusters #9, #12 and #13, corresponding to AML classes of inv(16), t(15;17) or t(8;21) respectively; c) establishing the similarity of the level of expression of said at least five cluster-specific genes in said subject to the level of expression of said genes in patients selected from an established AML class selected from the group consisting of inv(16), t(15;17) and t(8;21); and d) assigning to said subject a prognosis based on the similarity of level of expression of step c) corresponding to the established AML class, **does not** reasonably provide enablement for A method for determining the prognosis for an AML affected subject, said method comprising the steps of: a) determining, by means of assays conducted on a substrate, a level of expression for each of at least five cluster-specific genes selected from one of the clusters #9, #12 and #13, corresponding to AML classes of inv(16), t(15;17) or t(8;21) respectively; b) establishing the similarity of the level of expression of said at least five cluster-specific genes in said subject to the level of expression of said genes in patients selected from an established AML class selected from the group consisting of inv(16), t(15;17) and t(8;21); and c) assigning to said subject a prognosis based on the similarity of level of expression of step e) corresponding to the established AML class. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a method for determining the prognosis for an AML affected subject, said method comprising the steps of: a) determining, by means of assays conducted on a substrate, a level of expression for each of at least five cluster-specific genes selected from one of the clusters #9, #12 and #13, corresponding to AML classes of inv(16), t(15;17) or t(8;21) respectively; b) establishing the similarity of the level of expression of said at least five cluster-specific genes in said subject to the level of expression of said genes in patients selected from an established AML class selected from the group consisting of inv(16), t(15;17) and t(8;21); and c) assigning to said subject a prognosis based on the similarity of level of expression of step e) corresponding to the established AML class.

The specification teaches that samples were obtained from patients with a confirmed diagnosis of AML for gene profiling expression and correlation of gene expression in known AML karotype classes. The specification teaches that all inv(16) AML patients clustered within gene cluster #9. The specification teaches that Cluster #12 contains all cases of acute

promyelocytic leukemia (APL) with t(15; 17). The specification teaches that all patients with a t(8;21) grouped within cluster #13 See Examples 1 and 2. The specification teaches that five clusters (#5, #9, #10, #12 and #13) of 20 or more cases were evaluated in relation to outcome of therapy. The specification teaches that clusters #9 (CBFβ/MYH11), #12 (PML/RARα) and #13 (AML1/ETO), comprised cases with a favorable response to therapy. See Example 1 and 2.

One of skill in the art could not practice the method as claimed because the claims do not recite the critical step of taking a sample from the AML affected subject. Without obtaining from the AML affected subject the method is not enabled because the level of expression of the claimed genes could not be determined. Thus, the obtaining of a sample from an AML affected subject is critical to the performance of the method. In the absence of recitation of the critical step of obtaining of a sample from an AML affected the claims are not enabled. See MPEP 2164.08(c).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoch et al. (PNAS July 23, 2002, 99(15): 10,008-10,013).

Schoch et al. teach that a favorable out come is observed for patients with acute myeloid leukemia (AML) under current treatment regimens with the following karyotypes: 1) t(8;21 (q22;q22); 2) inv(16)(p13q22); and 3) t(15;17)(q22;q11-12). See p. 10,008-1st col. Schoch et al.

teach performing Affymetrix GeneChip analysis to determine the gene expression patterns of 37 AML patients with said karotypes. See p. 10,008-10,009. Schoch et al. teach comparing and classifying the patients' gene expression patterns to classify the samples into the aforementioned prognostic karyotype classes. See p. 10,009-10,011, Figs. 1-3 and Tables 1 and 2. Schoch et al. teach that the expression of the genes PTGDS, MYH11, ARHGAP4, ADRA2C, CBFA2T1, DKFZP564K0822, POU4F1 and TGFBI, which are part clusters #9, #12, and #13 of the instant application, were determined as part of the comparison and classification of the samples into the prognostic AML subtypes. See Table 2.

9. Claims 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohlmann et al. (Genes, Chromosomes, & Cancer 2003 37: 396-405).

Kohlmann et al. teach that prognostically relevant subtypes of acute myeloid leukemia (AML) have been established including the karyotypes: 1) t(8;21); 2) inv(16)(p13q22); and 3) t(15;17). See abstract, p. 396-1st col., and Table 1. Kohlmann et al. et al. teach performing Affymetrix GeneChip analysis using U95Av2 and U133A GeneChips to determine the gene expression patterns of 65 AML patients with said karotypes. See abstract, Table 1 and p. 397. Kohlmann et al. teach comparing and classifying the patients' gene expression patterns to classify the samples into the aforementioned prognostic karyotype classes. See p. 397-401, Tables 1 and 2, and Fig. 1. Kohlmann et al. teach that the expression of the genes CACNA2D2, CD81, TRH, MYH11, ARHGAP4, CBFA2T1, and POU4F1 and, which are part clusters #9, #12, and #13 of the instant application, were determined as part of the comparison and classification of the samples into the prognostic AML subtypes. See Table 2 and Fig. 1.

Although Kohlmann et al. does not specifically teach the expression of all the genes specifically named in claims 52-54 were analyzed, given that Kohlmann et al. teach that the expression of the 22,000 genes in the U133A Affymetrix GeneChip were analyzed in all specimens, see abstract, and these are the same chips used in the instant application, see p. 40 of the instant application, Kohlmann et al. would have assayed the expression of the genes in claims 52-54.

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER J. REDDIG whose telephone number is (571)272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/
Primary Examiner, Art Unit 1642